

PSJ3
Exhibit 639



Via Email: Robert.Brown@andanet.com

November 12, 2015

Robert I. Brown, Director
Regulatory Compliance, ANDA
2915 Weston Road,
Weston, FL 33331

Dear Mr. Brown:

Please find attached a report regarding a Suspicious Order Monitoring (SOM) Assessment conducted at ANDA by BuzzeoPDMA Consulting Manager, Robert Williamson and IMS Health Statistician Michael Liu on October 20 and 21, 2015. The review included ANDA's due diligence programs, SOM SOPs, discussions relating to order calculations and interviews with staff regarding the firm's corporate interaction with the Drug Enforcement Administration (DEA). [REDACTED] Additional recommendations are offered in terms of industry "best practices" and BuzzeoPDMA experience with clients.

Please let me know if you need clarification on any issues. Also, please feel free to contact Manager Williamson regarding the report or any other controlled substance questions or consulting needs.

Sincerely,

Ronald W. Buzzeo
Ronald W. Buzzeo, R.Ph.
Chief Regulatory Officer



**ANDA Incorporated
2915 Weston Road
Weston Florida**

SUSPICIOUS ORDER MONITORING ASSESSMENT

INTRODUCTION

On September 17, 2015, BuzzeoPDMA Now Part of IMS Health entered into an agreement with Actavis to conduct a Suspicious Order Monitoring (SOM) Assessment of ANDA's SOM compliance program. The intent of the project was to provide recommendations for enhancing ANDA's SOM model. Included in the review as described in the agreement were SOM items such as new and ongoing customer "due diligence" activities, corporate SOM procedures, SOM order entry procedures, including SOM modeling techniques, order investigation and clearing, and reporting practices.

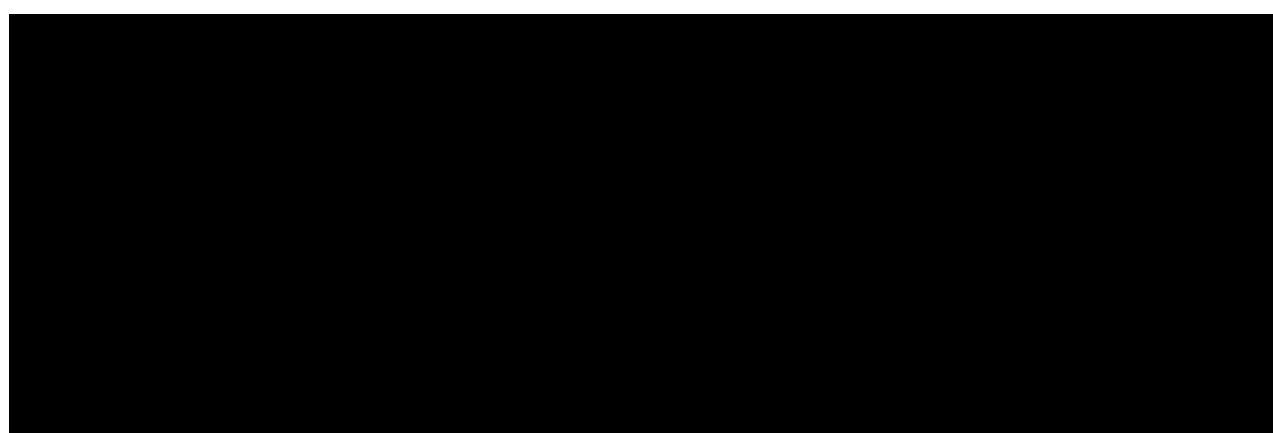
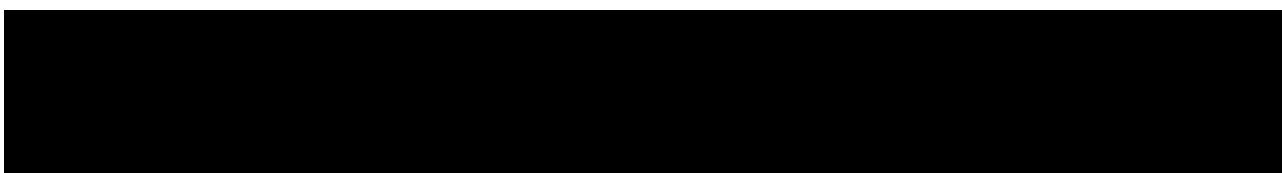
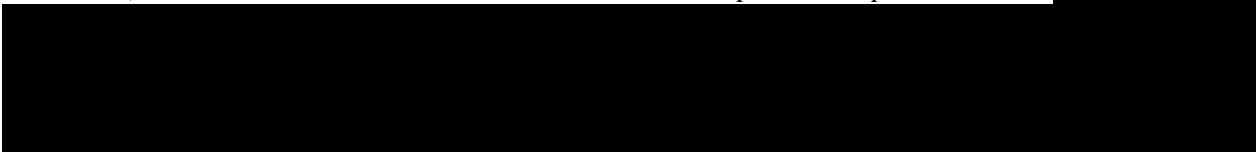
On October 20 and 21, 2015, Robert C. Williamson, Manager, DEA Consulting, BuzzeoPDMA and Michael Liu, Statistician, IMS Health, visited ANDA at the firm's corporate headquarters in Weston, Florida. Robert Brown the Director of Regulatory Affairs at ANDA was the lead point of contact for the review. Director Brown provided background information, including SOM procedures for the review and organized a series of meetings with ANDA's SOM staff to allow consultants to observe SOM procedures at ANDA "first hand." Tom Napoli, CPP, Associate Director, Actavis, Controlled Substance Compliance was also present as an observer. Michael Cochrane, Executive Director, Regulatory Compliance, ANDA, provided Consultants with corporate SOM background information and was involved with portions of the review. There was an opening and closing meeting with the aforementioned individuals and Charles Phillips, President.

ANDA is a "secondary" drug wholesaler, meaning that most of their customers purchase controlled substances from other suppliers and order from ANDA when they cannot purchase from their "primary" suppliers. Secondary suppliers have DEA SOM challenges since they do not have a history of interactions with customers or their interaction is sporadic. The firm is the primary supplier for Publix and the sole secondary supplier for Walgreens.

As noted, the Weston distribution facility is the corporate headquarters. ANDA management reported that the firm also has distribution facilities in Groveport, Ohio and Olive Branch, Mississippi. There are approximately 750 employees, corporate wide. According to Director Brown, the firm services approximately 20,000 which are roughly divided equally between retail accounts and chain accounts. Of the retail accounts, only around 1500 receive controlled substances. All SOM activities are conducted at the corporate headquarters. According to staff, the firm's growth is mostly driven by shipping non-controlled items. The firm has five SOM employees who report to the Director and Executive Director of Compliance.



ANDA provided BuzzeoPDMA Consultants with extensive information and documentation pertaining to corporate interaction with the DEA regarding SOM issues dating to 2007 when ANDA and Watson employees were invited to DEA Headquarters to discuss ANDA's SOM procedures. From 2007 continuing sporadically through this year the DEA has appeared to have an interest in ANDA's SOM program. Although there have not been any major official sanctions, the DEA has conferred with ANDA leadership on multiple occasions.



ANDA is asking BuzzeoPDMA to review their SOM system as an outside party to determine whether there are gaps or areas that could be improved.

SOM REGULATORY FOUNDATION

The regulatory foundation for suspicious order monitoring is contained in the following regulation:

§1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious

BuzzeoPDMA

Now Part of IMS Health

orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Information contained in the regulations has been embellished by the DEA through communications furnished to registrants in 2006 and 2007. These “SOM letters” establish expectations for greater registrant customer oversight and reporting; however, neither the language of the regulation nor the DEA “SOM letters” provide a specific roadmap for DEA registrants to follow to be assured of compliance with the regulation. In correspondence to registrants dated 12.27.2007, the DEA states that “... the DEA does not approve or otherwise endorse and specific system for reporting suspicious orders.”

BuzzeoPDMA Recommends those clients develop their SOM systems to address each of the following elements:

- An aggressive “know your customer” program to be assured that controlled substance products are not being distributed to inappropriate customers or that the firm’s products are not improperly distributed by others in their supply chain (“downstream distribution”).
- An order entry system that seeks to determine whether orders are of unusual size, of unusual frequency and/or deviate from a normal pattern.
- Procedures to identify and “pend” orders that are possibly suspicious; investigate the “pended” orders, document the investigation of the orders, and report the orders to the DEA if required.
- Implementation of on-site customer reviews as required.
- Development of SOPs that describe the registrant’s SOM program, processes and procedures
- A “culture of compliance” that recognizes the drug abuse potential of the products the registrant handles and supports employee actions as necessary for fulfilling SOM regulatory requirements.
- Management and staff regulatory training programs

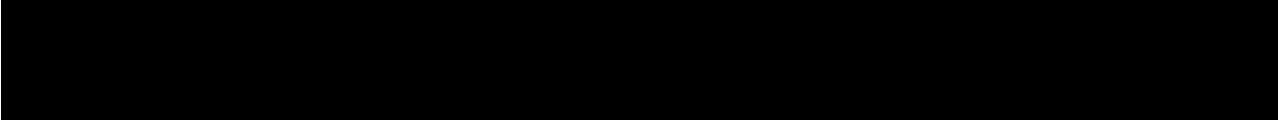
ANDA “KNOW YOUR CUSTOMER” PROCEDURES

New accounts are identified via ANDA’s sales and marketing processes. An account must be open for three months before the account may initiate a request to order controlled substances. ANDA uses a questionnaire to provide background information on all new customers. A sales representative will usually forward the questionnaire to the customer. The questionnaire is four pages long. There is an additional page for the owner to attest to his understanding of the

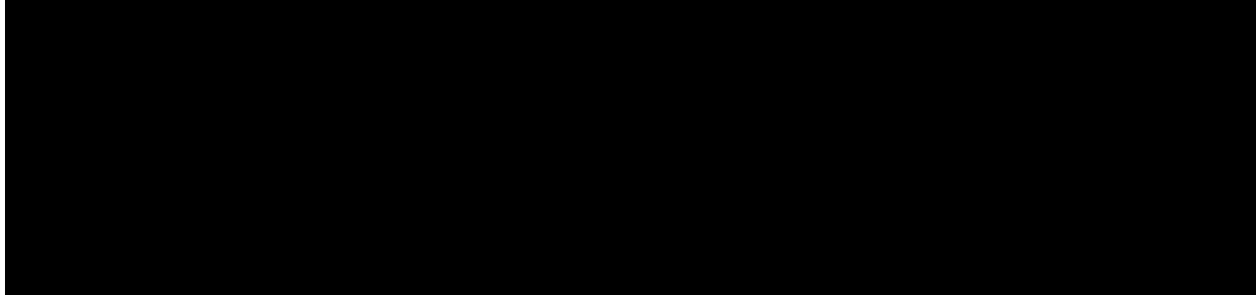
BuzzedPDMA

Now Part of IMS Health

regulations. The questionnaire and attestation page are common to many found in industry.



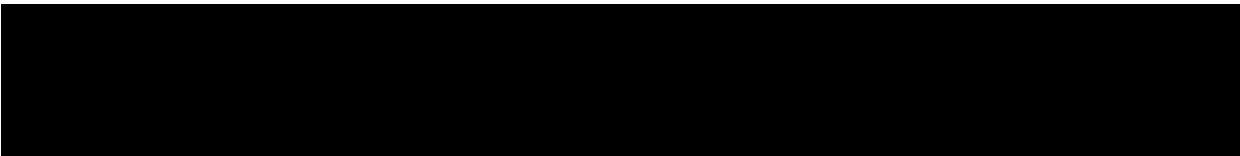
According to staff, questionnaires are mostly received electronically.



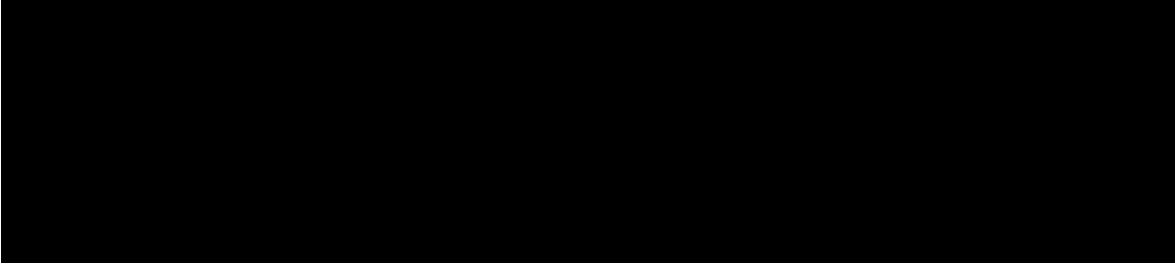
The process used to investigate these new applications is referred to as the “remedy review” process. As a matter of policy,



SOM employees report to Regulatory Compliance Director Robert Brown. It was reported that his staff will determine whether to allow a customer to order controlled substances and/or adjust their purchase levels after initially authorized, although the account sales representative will communicate the information to the account.



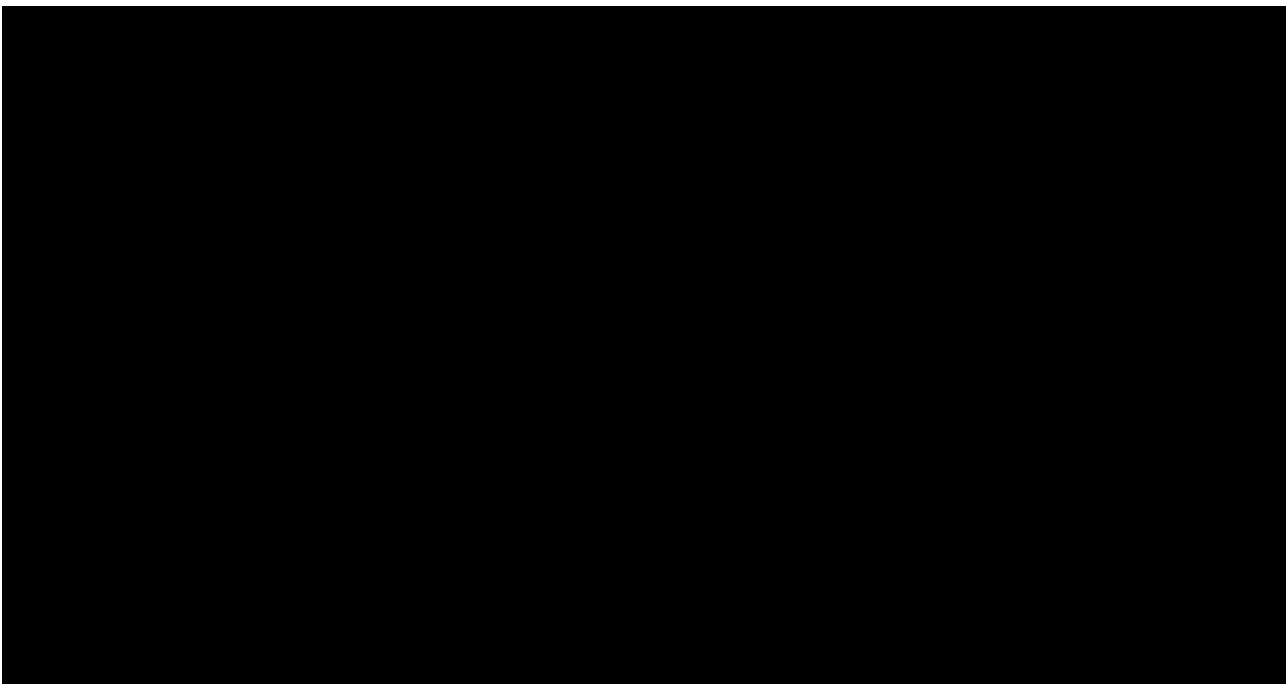
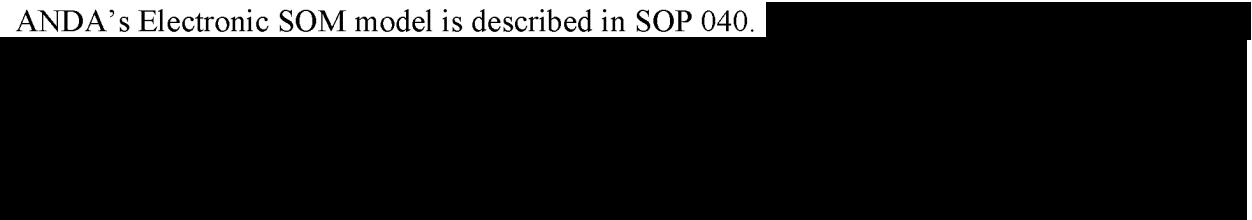
Finding and Recommendations

- -
 -
- 



ELECTRONIC ANALYSIS OF ORDERS

ANDA's Electronic SOM model is described in SOP 040.



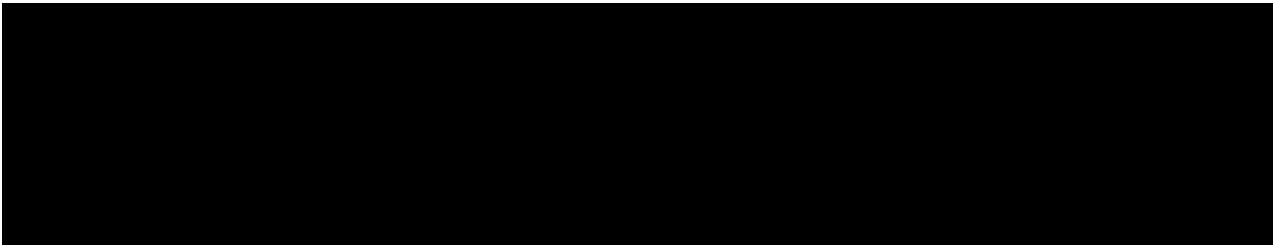
Findings and Recommendations

- 
- 
- 
- 



- [REDACTED]
- [REDACTED]
- [REDACTED]

REVIEW OF ORDERS



The “Remedy Review Process” was described to Consultants by individual staff members who opened computer screens to show the information on file and then discuss the types of things that they do for various account types in terms of investigating the order and resolving/adjudicating the issue. Information regarding the remedy review process is also described in SOP 045, which was made available to BuzzeoPDMA Consultants prior to the visit.

Investigative procedures as listed in SOP 045 are summarized as follows:

- [REDACTED]
- [REDACTED]

BUZZED PDMA

Now Part of IMS Health

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

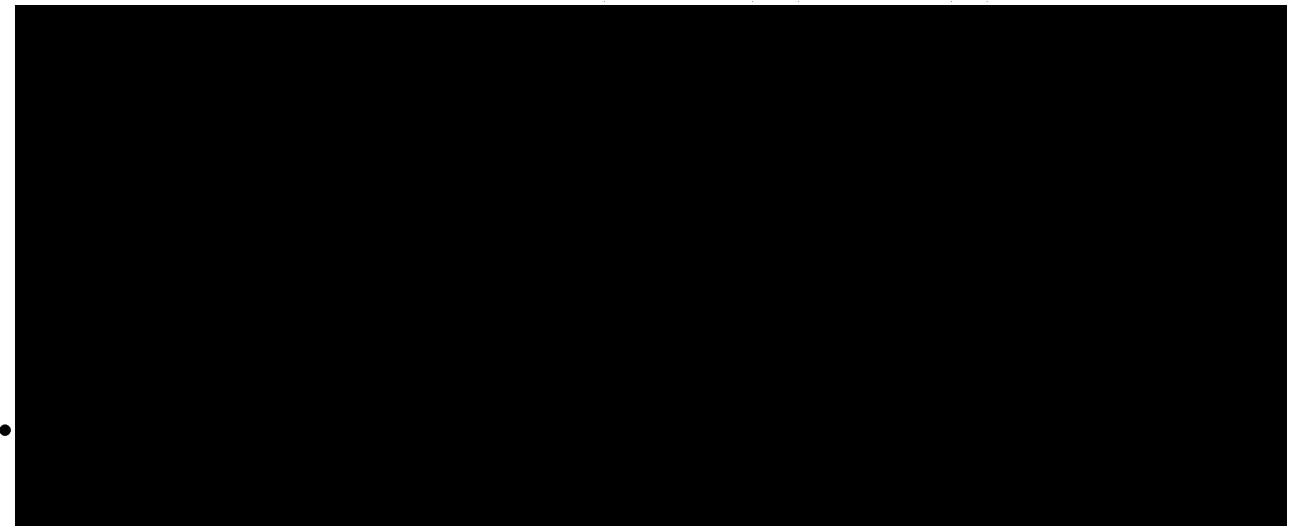
Consultants observed real electronic files that were used to document due diligence activity for new accounts and other types of order adjustments. It appeared through interviews with staff that ANDA's SOM staff used [REDACTED]

[REDACTED]

[REDACTED]

Findings and Recommendations

- [REDACTED]
- [REDACTED]



ANDA's SOM SUPPORT AND CULTURE OF COMPLIANCE

Consultants determined through interviews with staff and an examination of provided documents that ANDA supports regulatory oversight for the SOM process. As noted throughout, there is a well-defined SOM organization with training and support for SOM review activities.

According to management and staff, the sales staff interacts with customers on a frequent basis and is involved in communicating SOM issues to customer pharmacies, as would be expected. However, the Regulatory Department has the final say on whether an account will be authorized to order controlled substances and/or what the threshold is. ANDA management reported that there are periodic meetings with sales and regulatory; however, it was reported that specific information regarding the investigation of accounts and orders was not shared with the sales representatives.

From a broader perspective, ANDA does have some initiatives in place to foster employee sensitivity to drug abuse issues and the firm's responsibility to sell controlled substances responsibly. The firm does have a "Drug Free Work Place" policy; however, it is included in the firm's Standards of Conduct and not visibly promoted internally. The firm also requires pre-employment and "for cause" drug testing.

ANDA also participates in a program called "It Starts with Me" which was developed by Actavis. This is a program developed to promote drug abuse prevention initiatives through company support and community outreach.

As can be surmised in the program's title, "It Starts with Me" encourages employees to recognize the importance of drug abuse prevention and control regulations and further encourages employees to work in the community through ongoing corporate relationships with key community educators and stakeholders.



Program Highlights as noted in information provided to Consultants are listed as follows:

- The relationship between diversion prevention and successful operations and the public interest
- Workplace behaviors that promote the secure handling of controlled substances throughout the product lifecycle
- One's personal obligations under the compliance program
- Compliance with regulatory requirements

Director Brown also furnished follow up information after the on-site review regarding ANDA's initiatives to train pharmacists on controlled substance issues. ANDA has provided a grant to develop a course for pharmacists with "continuing education credits." The goal of the course as noted in the provided informational materials is to "provide pharmacists with tools and tips on fulfilling their role in appropriate controlled substance dispensing." Director Brown indicated that 3000 pharmacists have taken the course. It was also noted in the materials provided that the program will expire in December of 2015.

Findings and Recommendations

- [REDACTED]
- [REDACTED]

QUALIFICATIONS

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.
2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations, and our experience with them. Many of the requirements of the CSA and regulations thereunder are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this in mind.
3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations.